

**Comments and Responses on Proposed Changes to
Vermont's Policy on Patient Consent for Provider Access to Protected Health Information on VHIE**

Nature of Comment	Commenter(s)	Responses
<p>Patient Rights – a number of commenters requested clearer policies around information provided to patients concerning their rights under the Policy, including audit requests.</p>	<p>VT ACLU HIV/AIDS providers Sue Prent Planned Parenthood</p>	<p>We agree it may clarify the Policy to add the word “receive,” such that the language would read: “An individual may request and receive an Audit Report of access to his or her PHI...” A patient may request and receive an audit report at any time.</p> <p>We have also added language into Section 3(b) requiring that information regarding all patient rights be included in educational materials and resources.</p>
<p>Global v. Provider-by-Provider Opt In – several commenters argue against the proposal to change from consent being given provider by provider to a “global” consent that will permit access to that individual’s protected health information (PHI) by all participating providers involved in his or her treatment.</p>	<p>Office of Health Care Advocate (HCA) Cathy Walker</p>	<p>We support the global opt-in policy because:</p> <ul style="list-style-type: none"> • Significant information educational materials are required to be made available to patients before they decide whether or not to consent • Patients can opt out at any time • Better care and lower costs are possible with more and better information • Timely communication of patient information to providers will be enhanced • Patients will not have to give their consent multiple times • It will be less burdensome on providers
<p>Warrant Requirement for Law Enforcement Access to Patient Records – several commenters stated that law enforcement must be prohibited access to medical records without a warrant.</p>	<p>VT ACLU HIV/ AIDS providers Sue Prent</p>	<p>These commenters appear to be requesting protections in addition to existing law, which would require legislative action and cannot be accomplished through the consent policy.</p>

<p>Enforcement and Penalties – several commenters stated that stiff civil and criminal statutory penalties must be created that can be imposed on any person or institution accessing a patient’s records without authorization or need to do so.</p>	<p>VT ACLU HIV/ AIDS providers Sue Prent HCA Planned Parenthood</p>	<p>Changes in law and enforcement policies since the passage of the federal HITECH Act (part of the federal ARRA legislation in 2009) have resulted in significant criminal and civil penalties for violating HIPAA. In addition, the Vermont Attorney General’s office is now authorized under the HITECH Act to enforce the HIPAA privacy regulations through injunction or civil penalties.</p> <p>New penalties would require legislative action and cannot be accomplished through the consent policy.</p>
<p>Private Right of Action – several commenters requested that a private right of action be created for patients to sue for damages for unauthorized access to records.</p>	<p>VT ACLU HIV/ AIDS providers Sue Prent HCA</p>	<p>This change would require legislative action and cannot be accomplished through the consent policy.</p> <p>HIPAA is a federal law and does not provide an individual right of action. The HIPAA Regulations create a system which allows individuals to make complaints to OCR about potential violations, and the HIPAA Regulations require covered entities and business associates to develop a process to review complaints about such violations. As of 2009, HIPAA also requires covered entities to self-report all privacy and security breaches to the patient and the Office of Civil Rights</p>
<p>Drug and Alcohol Treatment Information – several commenters expressed concern about whether and how the Policy should address 42 CFR Part 2 – Drug and Alcohol Treatment Information.</p>	<p>HCA VT Agency of Human Services</p>	<p>The handling and exchange of drug and alcohol treatment information, addressed in 42 CFR, Part 2, is a challenge. The exchange of this information is a very important to individuals’ treatment. However, additional work is needed to determine the appropriate policy to support the exchange of this data in ways that will comply with Part 2.</p> <p>The resolution of the 42 CFR Part 2 health information exchange issues will require the full and deep engagement of the State, VITL and others. The state will engage with others to undertake this project. We have therefore added language to this effect into the Policy and removed language which VITL is not able to implement at this time.</p>

<p>Operational and Educational Issues – many comments were received with questions and concerns about how the health information exchange systems and patient consent processes will work, including regarding education materials, consent forms, revocation procedures, user sign-in procedures, inappropriate access, etc.</p>	<p>VT ACLU HCA Rutland Regional Medical Center Planned Parenthood</p>	<p>All involved agree on the importance of good upfront information, training materials, and operational procedures, and many have been developed as part of early pilot projects. However, we do not agree that the many details of these materials and processes should be included in the Policy. Improvements and updates will be made regularly and the formal processes involved with revisions to the Policy would delay timely updates.</p> <p>We agree that more and better communication and engagement with stakeholders should occur.</p> <p>It is worth noting that access to any Exchange system can and will be controlled based on readiness, training, acceptance of policies and procedures, appropriate roles, and use of usernames and passwords.</p>
<p>Minors – one commenter states that the right to access and audit patient records should include appropriate protections for minors.</p>	<p>HCA</p>	<p>The consent form materials used in the VITL Pilot required the consent of both the parent and any minor age 12 or older prior to provider access to the VHIE. Guidance for handling patient/parent VHIE access requests will be developed and made available to participating healthcare providers.</p>